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CLINICAL RESEARCH

Cross-analysis of dietary prescriptions and adherence in 356 hypercholesterolaemic patients

Analyse croisée des prescriptions diététiques hypocholestérolémiantes et de l'observance chez 356 patients

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KEYWORDS

Adherence;
Diet;
Hypercholesterolaemia

Summary

Background. — One of the major issues in controlling serum cholesterol through dietetic intervention appears to be the need to improve patient adherence.

Aims. — To explore the many questions regarding barriers to, and motivators for, cholesterol-lowering diet adherence.

Methods. — We surveyed French general practitioners' dietetic practices for patients with hypercholesterolaemia, and looked at their patients' attitudes towards such an approach.

Results. — We analysed 234 doctors' personal questionnaires and 356 patient self-survey questionnaires. Patients' reasons for not complying with the prescribed diet included: 'already having satisfactory food habits' (34.7%), 'unwillingness to suffer nutritional deprivation' (33.3%), 'difficulties to conciliate a diet with family life' (27.8%) and 'taking cholesterol-lowering drugs' (22.2%). Despite a generally good understanding by patients of doctors' recommendations, some discrepancies were seen between their respective declarations. While doctors largely thought that patients needed more explanation on why and how a diet can lower cholesterol (and avoid taking drugs), only 39.4% of patients declared needing this kind of information. Other discrepancies were observed concerning barriers to, and motivators for, patient

Abbreviations: CHD, coronary heart disease; CVD, cardiovascular disease; HAC, hierarchical ascendant classifications; LDL-c, low-density lipoprotein cholesterol; PCA, principal component analysis.

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MOTS CLÉS

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adherence. Moreover, some dietetic rules appeared to be more difficult to comply with than others, e.g. 82.6% patients remembered they should 'eat more fish' but only 51.3% actually did so. Finally, physicians, as well as patients, displayed a lack of confidence in lipid-lowering diet efficiency.

Conclusion. — Improving patient education, especially concerning their perception of risk, as well as increasing the involvement of dietitians, are motivators to explore in order to improve adherence.

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Résumé

Contexte. — L'amélioration de l'observance et le respect des prescriptions diététiques par les patients sont des problématiques majeures dans le suivi des régimes hypocholestérolémiants.

Objectif. — Explorer les nombreuses questions relatives aux freins et aux leviers agissant sur l'observance des régimes hypocholestérolémiants.

Méthodes. — L'étude a observé les pratiques des médecins généralistes français auprès de leurs patients hypercholestérolémiques et les attitudes de ces derniers vis-à-vis de la prescription.

Résultats. — Deux-cent-trente-quatre questionnaires personnels des médecins et 356 auto-questionnaires des patients ont été analysés. Les premières réponses invoquées par les patients (traités ou non traités) sur les raisons de leur non-observance du régime prescrit étaient : « ayant déjà des habitudes alimentaires satisfaisantes » (34,7% des interrogés), réticence aux privations (33,3%), difficultés à concilier le régime avec une vie familiale (27,8%) et prise de médicaments hypocholestérolémiants (22,2%). Malgré la bonne compréhension générale des patients vis-à-vis des recommandations des médecins, des divergences ont été observées entre leurs déclarations respectives : alors que la plupart des médecins pensaient que les patients avaient besoin davantage d'explications sur pourquoi et comment un régime peut faire baisser le cholestérol (et éviter le traitement médical), seuls 39,4% des patients déclaraient en avoir besoin. D'autres divergences ont été constatées au sujet des freins et des leviers agissant sur l'observance. Par ailleurs, certaines règles diététiques semblent plus difficiles à respecter que d'autres : par exemple, 82,6% des patients se rappellent devoir « manger plus de poisson » mais seulement 51,3% le mettent en pratique. Enfin, les médecins tout comme les patients montrent un manque de confiance dans l'efficacité des régimes hypolipidémiques.

Conclusions. — L'amélioration de l'éducation des patients, notamment sur la perception des risques, mais également le renforcement de l'implication des diététiciens, sont des leviers à explorer pour améliorer l'observance.

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Background

Decreasing low-density lipoprotein cholesterol (LDL-c) to an adequate target level can significantly reduce the risk of suffering a first coronary event [1]. Even a small decrease in total cholesterol may prevent a large number of such events. Indeed, a large study conducted in the US demonstrated that a major decrease (44%) in deaths from coronary heart disease (CHD) was attributable to changes in risk factors, including a 24% decrease due to a 6% reduction in total cholesterol [2].

A broad base of evidence supports recommendations for lifestyle changes for LDL-c-lowering therapy in primary prevention [1]. A more recent study has also confirmed that dietary interventions actually reduce risk factors for cardiovascular disease (CVD) and can be implemented in practice [3]. Among the therapeutic lifestyle changes aimed at reducing the risk of CHD, reduced intakes of saturated fats and cholesterol, as well as other therapeutic dietary options for lowering LDL-c (plant stanols/sterols and increased viscous fibre), are recommended to reach the LDL-c objective [1].

Hence, in hypercholesterolaemic patients, the goal of reducing cholesterol and improving risk factors can be achieved by improving food habits even slightly. However, patient adherence to dietary recommendations, which is essential to 'make it work', is difficult to achieve. Despite some recent improvements in knowledge about cholesterol, patient adherence to cholesterol treatment recommendations remains sub-optimal [4]. Numerous studies have addressed this issue specifically [5–8]. Others have tried to intervene upstream by understanding barriers to adherence, which can be multiple and vary from person to person [9]. Barriers relate to patients as well as to doctors [10], placing the doctor–patient relationship at the core of the problem, and its solution.

However, various questions remain unanswered. Is the doctor's perception of patient adherence accurate? What are the obstacles to/motivators for cholesterol-lowering diet adherence? What are the motivators for improving cholesterol-lowering dietary recommendations? To help answer these questions, the present study surveyed French general practitioners for their dietetic practices for patients

with hypercholesterolaemia, and their patients' attitude towards such recommendations.

Methods

Study design and participants

In this multicentre, prospective, observational study, hypercholesterolaemic patients were recruited by a representative sample of general practitioners in France.

General practitioners were recruited randomly from the Danone Santé database by an independent company. Within a 1-month period, each practitioner had to include two hypercholesterolaemic adult (≥ 18 years) patients; one had to be on a cholesterol-lowering medication and one had to be medically untreated.

Both patients had to have been diagnosed 1 to 6 months beforehand with hypercholesterolaemia (LDL-c > 4.1 mmol/L). Patients were excluded if they: were participating in another clinical trial; presented with coronary heart disease, cerebrovascular disease or symptomatic peripheral vascular disease; or were following an atypical diet.

Questionnaires

A series of questions was developed following several 3-hour focus group sessions, involving a total of eight general practitioners and 24 patients, recruited from two and three French regions, respectively. Three questionnaires were developed ([Appendix A](#)):

- the doctors' personal questionnaire concerned personal data (gender, age, thesis date, geographical region of practice, proportion of patients with cardiovascular risk factors, difficulties encountered when prescribing a diet and opinion on principles facilitating patient adherence [0–10 scales]);
- the doctors' questionnaire on the patient concerned social and demographic data, date of diagnosis, family history of coronary heart disease, cardiovascular risks, biological data at hypercholesterolaemia diagnosis (serum cholesterol and triglycerides, cholesterol-lowering treatment, cholesterol-lowering diet, opinion on importance of compliance with diet and other recommendations [physical activity, stopping smoking, etc.]). This questionnaire was filled in by the doctor during the consultation;
- the patient self-survey questionnaire concerned personal data (age, gender, serum cholesterol figures, cholesterol-lowering medication, opinion on importance of compliance with diet for their health, current food habits, cholesterol-lowering diet, need for complementary information or specific aids to comply with the diet, opinion on importance of compliance with diet for lowering cholesterol, other recommendations from doctor and relative importance attached to various recommendations to fight cholesterol). The patient had to fill in the questionnaire at home, alone and without help from the doctor.

Objective

The primary objective was to assess actual dietetic care modalities and patient adherence for medically treated and untreated hypercholesterolaemic patients in general practice.

Sample size

To reach the primary objective, the principal criterion was the proportion of subjects presenting an adequate diet (defined beforehand by the Scientific Committee according to a benchmark calculated on the basis of food habits described in the patients' self-survey questionnaire). Because of lacking data, the hypothesis was that this proportion would reach 50% of subjects. To estimate the actual proportion in medically treated and untreated groups with a 95% confidence interval and a 5 to 10% absolute precision for the whole sample, 267 subjects were needed in each group (medically treated and untreated).

Statistical analysis

Multi-variable analysis was performed based on data collected from the practitioners' declarative questionnaires assessing their level of compliance, on a scale from 0 to 10, regarding different opinions related to dietary recommendations (barriers and motivators).

Principal component analysis (PCA) was performed to determine links between the studied variables, the existence of correlated groups of variables, and to highlight variables that would characterize different homogeneous groups. Several PCAs were performed, first on the raw marks (0–10) given to the studied variables, then on the standardized marks,

Then, hierarchical ascendant classifications (HAC) were performed based on the first three factors resulting from the PCA. The objective was to split practitioners into subgroups, each one characterized by homogeneous behaviour regarding dietary recommendations (practitioners' typology).

All analyses were performed with SPSS Version 11.0.

Results

Patient population

A total of 488 hypercholesterolaemic patients were recruited by 239 general practitioners in France between 2nd April and 15th May 2006. Only 236 physicians included two patients, as specified in the study protocol. A total of 488 patients were included in the study, of whom 475 had an available inclusion questionnaire, and 434 were selected (all inclusion criteria met) for descriptive analysis of the inclusion phase. Patient characteristics at inclusion are shown in [Table 1](#). Among these patients, 356 had both analysable inclusion questionnaires (filled in by the doctors) and self-survey questionnaires, and were selected for further descriptive analysis.

Table 1 Characteristics of the study patient population at inclusion, according to whether or not they were taking medical treatment for hypercholesterolaemia ($n = 434$).

	Treated ($n = 226$)	Untreated ($n = 208$)	p
Men	65.5	51.9	0.004
Age (years)	57.8	53.9	0.03
Marital status			
Single	10.2	9.6	0.21
Married	72.4	67.8	0.21
Divorced or separated	3.6	9.1	0.21
Weight (kg)	80.8	74.9	< 0.001
BMI (kg/m^2)	27.8	26.3	0.002
Duration of hypercholesterolaemia (weeks)	17.2	13.1	< 0.001
Family history of early coronary heart disease	24.8	13.9	0.004
Personal risk factor(s) for cardiovascular disease			
≥ 1	84.5	65.9	< 0.001
≥ 2	69.1	42.3	< 0.05

Data are number (%) or mean.

Dietary recommendations and patient adherence

When asked 'Did you recommend a cholesterol-lowering diet to this patient?', doctors answered positively for 97.2% of their patients. Similarly, when asked 'Did your doctor recommend a cholesterol-lowering diet?', 98.2% of patients answered positively.

Doctors explained the diet once at the beginning more often in medically untreated patients (62.3% vs. 47.3%; $P = 0.002$), but gave dietetic advice regularly during successive medical visits more often in medically treated patients (60.9% vs. 46.2%; $P = 0.003$) (Table 2).

However, fewer patients reported having the diet explained once at the beginning, but more reported being

given advice during successive consultations and having their questions about food habits answered (Table 2).

Barriers to patient adherence

Answers to doctors' questionnaires inquiring about potential difficulties for patient adherence to the prescribed diet identified a general tendency in most physicians. Indeed, the most rated items, on a 0 to 10 scale, pointed out difficulties directly related to patients' attitude (Fig. 1). Among the reasons, many had to do with patients' lack of conviction about diet efficacy (drugs being more relevant) or about specificity/wisdom of doctor's advice (patients thinking they know better). Other reasons were related to patients' lack of motivation, with respect to nutritional

Table 2 Modalities for dietetic recommendations that doctors declared to have given and patients declared to have been informed about.

Modalities for recommendations	Doctors' report ($n = 406$)				Patients' report ($n = 269$)			
	Treated patients ($n = 207$)	Untreated patients ($n = 199$)	p	Total ($n = 406$)	Treated patients ($n = 147$)	Untreated patients ($n = 122$)	p	Total ($n = 269$)
Diet explained only once at the beginning	47.3	62.3	0.002	54.7	46.3	49.2	0.63	47.6
Dietetic advice given at the beginning and later during others consultations	60.9	46.2	0.003	53.7	64.6	54.9	0.11	60.2
Answers to patient's questions about his/her food habits	41.5	36.7	0.32	39.2	41.5	47.5	0.32	44.2

Data are given as percentage. The totals are > 100% as multiple responses were possible.

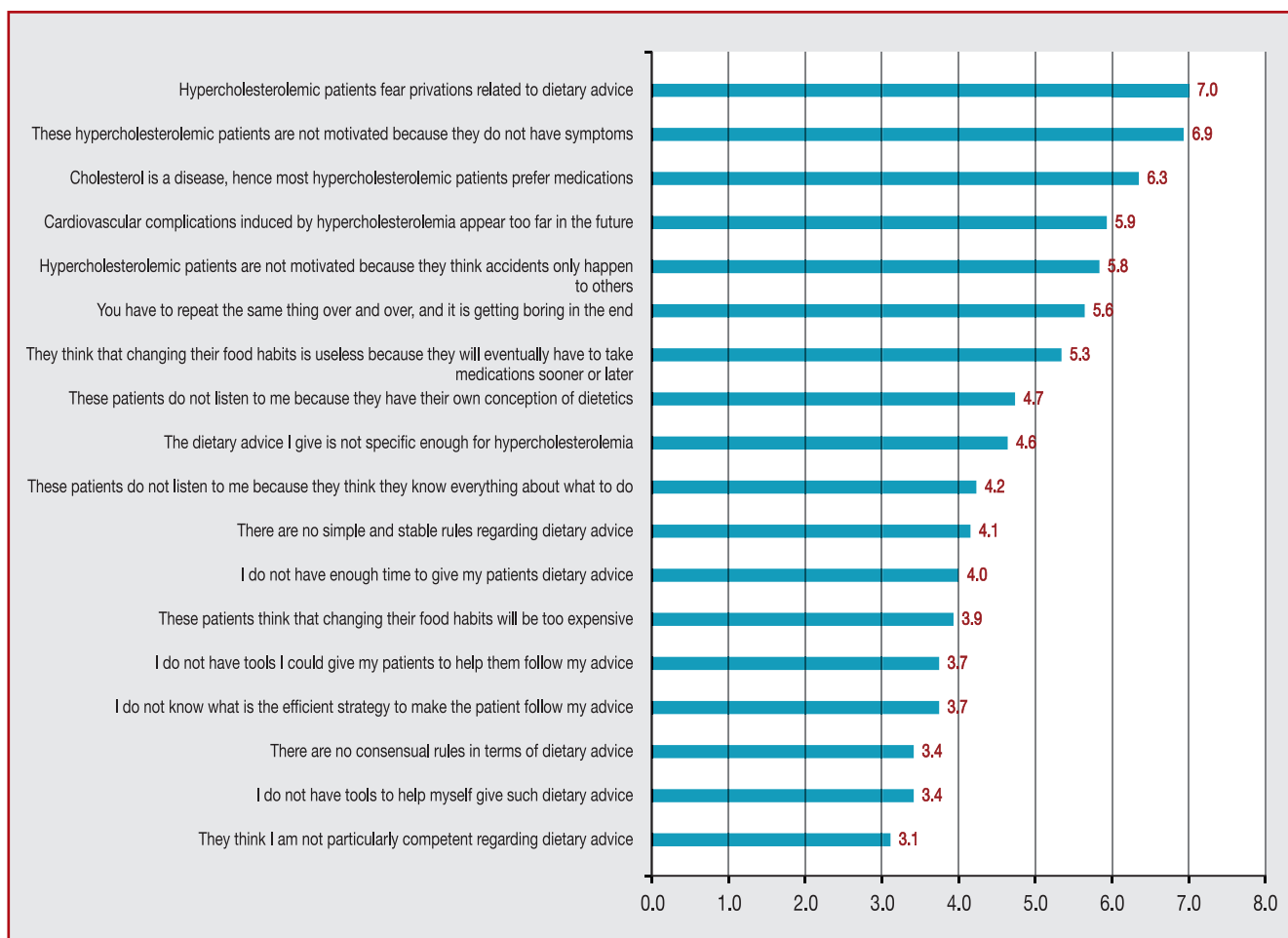


Figure 1. Potential difficulties reported by doctors to patient compliance with dietary prescription — breakdown of mean scores (doctors' adherence with various proposed items on a 0–10 scale).

deprivation induced by diet and being confronted with a 'silent' disease (no awareness of actual risks).

When patients (whether medically treated or untreated) were asked about the reasons for not complying with a prescribed diet, the four top answers were 'already having satisfactory food habits' (34.7%), 'unwillingness to suffer nutritional deprivation' (33.3%), 'difficulties to conciliate a diet with family life' (27.8%) and 'taking cholesterol-lowering drugs' (22.2%).

Facilitating principles for patient adherence to prescribed diet

No item clearly emerged from the mean grades rating the doctors' 'facilitating principles' questionnaire. The most graded items were often related to the explanation/demonstration of efficacy and benefits that could be expected from diet (e.g. 'Show them that a balanced diet may allow them to avoid medication' or 'Express benefits related to the modification of their food habits'), and to feasibility of an effective diet (e.g. 'Insist on the fact that controlling cholesterol in the long run is perfectly feasible with an appropriate diet'). Some rather psychological items also emerged (e.g. 'Identify what they are most attached to

and insist on related advice'), indicating that some doctors found it important to pay attention to a patient's psychology.

The doctors' questionnaire on 'facilitating principles' contained two categories of items: principles that were very 'directive', imposing and concrete (implying that they were directed to rather passive patients), and principles giving more priority to the relationship with the patient, implying a very careful handling of patients (which would be directed to more autonomous patients). Hence, answers to this questionnaire, from the PCA on the grades, and more so from the HAC on standardized grades, enabled two corresponding typologies of doctors to be identified: 'relation-oriented' and 'academic' physicians (Fig. 2).

Most patients (60.7%), whether medically treated or untreated, declared no need for information or help to conform to a diet. When asked to choose between various types of information, they opted for a reminder of recommended foods and foods to avoid or ways of cooking, and advice to modify everyday food habits (Table 3).

Hence, while doctors (in particular the 'academic' sub-population) largely thought that patients needed more explanations on why and how a diet can lower cholesterol (and avoid taking medication), only 39.4% of patients declared that they needed this kind of information. In addition, while 'giving practical documents, like diet recipes'

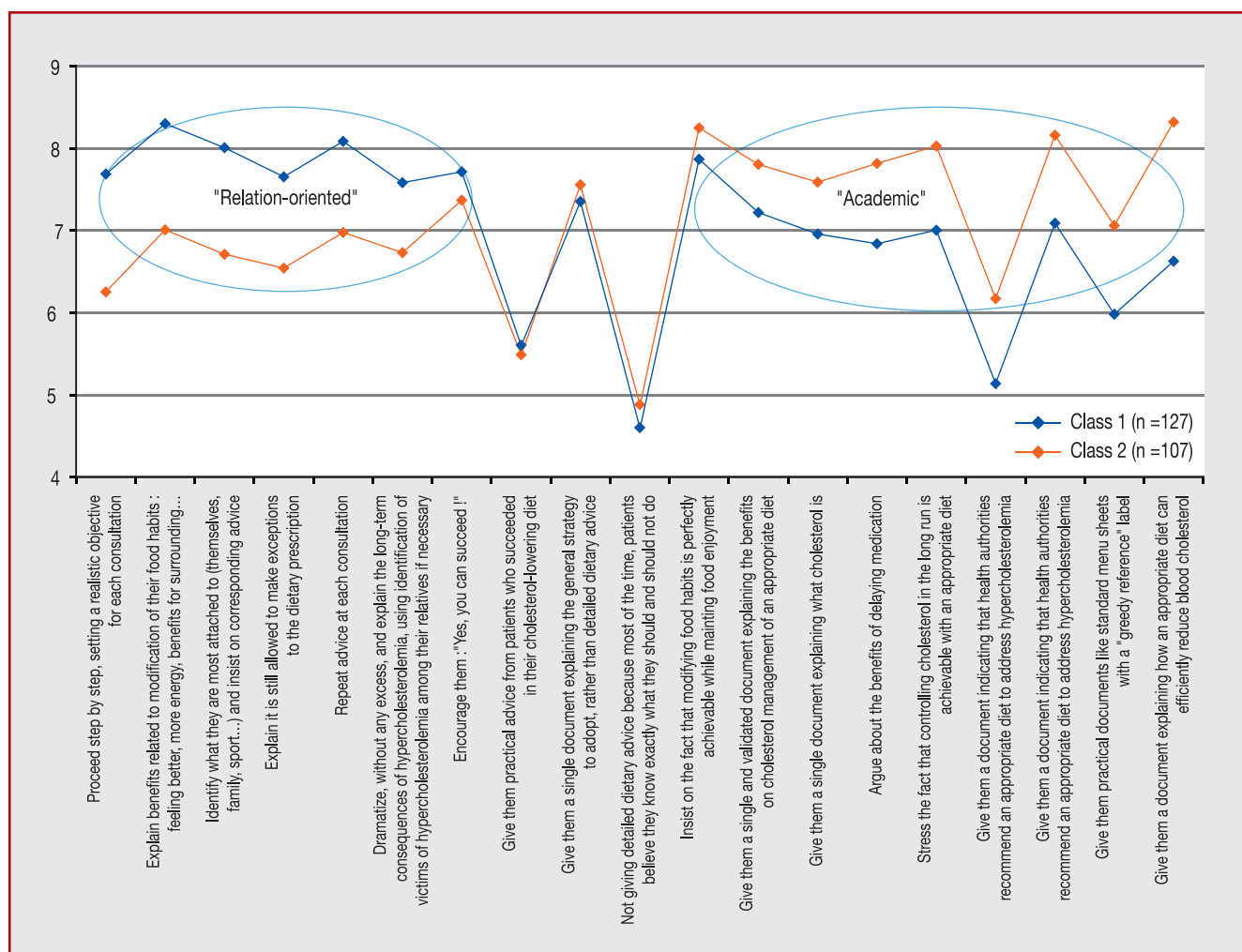


Figure 2. Two typologies of doctors ('relation-oriented' versus 'academic') identified from the HAC on the first three factors from the PCA (on standardized grades), applied to answers to the 'facilitating principles' questionnaire.

Table 3 Information needed by patients to help them with their diet.

	Treated and untreated patients (n = 137)
Cooking guide with advice on how to cook with less cholesterol	76 (55.5)
Official chart of recommended foods and foods to avoid when you have high cholesterol	76 (55.5)
Advice to modify everyday food habits	74 (54.0)
Recipe cards explaining how to prepare a menu adapted to hypercholesterolaemia	65 (47.4)
Document drawn up by renowned chefs with special recipes	60 (43.8)
Document explaining why and how a diet can lower cholesterol	54 (39.4)
Document explaining how to progressively modify my food habits	44 (32.1)
Other suggestions	8 (5.8)

Data are number (%). The totals are > 100% as multiple responses were possible.

Table 4 Adherence to dietetic advice: advised versus complied with rules.

Dietetic rules	Patients		Doctors
	Complied with (n = 273)	Recalled (n = 275)	Advised (n = 422)
Limit fatty meats and cured pork meats	79.5	89.1	93.5
Limit fatty dairy products	71.1	83.0	82.8
Eat more fish	51.3	82.6	89.7
Replace butter with vegetable oils	60.8	80.0	84.0
Limit pastries and cookies	73.6	78.1	79.9
Be careful about food in general	77.3	77.4	62.7
Eat more fruit and fresh vegetables	68.9	72.1	78.7
Do not eat more than 2 eggs/week	48.7	67.2	64.8
Eat less in general	47.3	58.9	49.0
Limit alcohol	48.7	55.8	55.0
Eat plant sterol rich food	26.7	46.4	40.9
Eat products containing cereal (e.g. wholemeal bread)	35.5	46.0	39.2
Limit salt	35.2	46.0	43.1
Other rules	2.2	5.7	6.7

Data are given as percentage. The totals are > 100% as multiple responses were possible.

was not considered by doctors as an effective facilitating principle, the majority of untreated patients said this would help them.

Opinions on patient compliance

On a 1 to 10 scale, where 0 meant 'not important at all' and 10 meant 'extremely important', doctors' mean score for the importance of a diet for their patients was 7.7, with a significant difference between medically treated (7.5) and untreated (7.9) patients ($P=0.049$).

For patients, on the same scale as for physicians, the importance of compliance with a diet for 'hypercholesterolaemic individuals' obtained a mean score of 7.3, with a significant difference between medically treated (7.1) and untreated (7.7) patients ($P=0.003$). When the same question was applied to themselves, the importance of compliance with the diet for their hypercholesterolaemia was graded 6.7, again with a small difference between medically treated (6.5) and untreated (7.0) patients ($P=0.01$).

Thus, both doctors and patients considered that diet is relatively important; particularly for medically untreated patients.

The reality of patient adherence to prescribed diet

Actual compliance (as declared by patients) with dietary rules revealed that the most recommended rule (according to both doctors and patients), which was limiting fatty meats and cured pork meats, was also the most obeyed (Table 4).

Discussion

The first observation following the results of the present study is that doctors attach some importance to dietetics in the primary care for hypercholesterolaemic patients, but also patients are, in general, aware of it. However, the importance of diet for patients' health remained underestimated by doctors, an observation that concurs with previous data in the literature [11–14].

Barriers to patient adherence, as considered by physicians, were both 'theoretical' (lack of conviction, in particular concerning the efficacy/usefulness) and 'practical' (fear of nutritional deprivation, difficulties with everyday and family life organization). In physicians' declarations, most barriers were considered to be related to patients. These findings concur with previous work [15].

The two main barriers cited by physicians and patients were patients' unwillingness to deprive themselves and a lack of motivation due to the absence of symptoms. Other studies have already demonstrated that nutritional recommendations are considered restrictive by patients [14] and that patients' lack of knowledge was an important barrier to adherence [11–14].

It is important to note the barrier that some patients thought they already ate well. This tendency was particularly found among medically treated patients, who were more likely to have been through diets (or at least dietary prescriptions). However, this patient opinion could also result from a lack of knowledge of dietetic rules, or from a lack of confidence in their general practitioner's dietetic competence.

Another barrier, mentioned in the present study by both physicians and patients, is patients' lack of conviction of the efficacy/usefulness of diet. This confirms the results of a survey which showed that, among the 89% of 3600 subjects involved who knew the existence of cardiovascular

prevention measures, only three out of four subjects thought prevention could be efficient, and less than two out of three were compliant to these recommendations (even less in smokers and obese people) [16]. Interestingly, in the present survey, patients doubting diet efficacy or usefulness tended to be more numerous among medically untreated patients who, compared to treated patients, could be less 'educated' about the disease.

However, physicians in the present survey also reported difficulties related to their own practice: the absence of specific or stable advice and a lack of time were the most cited, followed by a lack of strategy and tools to efficiently explain and help patients to comply durably with the diet. These results reveal, more than some previous works, a certain discomfort of general practitioners with giving dietetic advice, and underline a lack of specific knowledge concerning diet issues, in particular related to hypercholesterolaemia. Lack of time, however, has previously been reported as a major barrier (for 38% of all interviewed physicians) to implementing guidelines for hypercholesterolaemia, together with medication costs (30% of physicians) [11].

Motivators, or facilitating principles, were one of the rare elements for which doctors and patients seemed not to agree. Doctors thought that more explanations and demonstrations were needed to facilitate patient adherence, e.g. practical guidance aimed at helping patients to apply dietetic rules to their everyday life. Even if this demand is understandable and such adapted tools could, in fact, be truly helpful, patients' refusal for more information on disease and treatments in this study could reflect a sort of denial, especially in view of their lack of knowledge concerning the importance of diet for their health.

Generally speaking, physicians and patients reported similar dietetic recommendations (made versus heard). However, discrepancies appeared in the description of the modality of prescription. The diet was essentially explained only once to untreated patients, according to physicians, whereas according to patients, whether treated or untreated, the explanations were given little by little during successive medical visits.

Other surveys, such as the Reassessing European Attitudes about Cardiovascular Treatment (REACT) study, have indicated discrepancies between physicians' and patients' perceptions and actual clinical practice [11]. Again, such differences in perception and experience between physicians and patients generally indicate that physician–patient communication is sub-optimal and highlights the need to improve educational material for cardiovascular disease prevention [14].

The design of the present survey made a distinction between medically treated and untreated patients. For both doctors and patients, the diet appeared to be more important for untreated than for treated patients, who are supposed to be the most 'at risk'. The observation that doctors explained the whole diet just once to treated patients less often than to untreated patients may be due to the fact that medically treated patients were already supposed to know the dietetic rules. Indeed, according to official recommendations, a medical treatment can be started only after failure of diet to lower cholesterol to meet a defined target.

Limitations of this study include the fact that patients had to consent to participate in the study, and such patients may differ from the whole population of dyslipidaemic subjects. However, we tried to achieve patient representativeness by ensuring the representativeness of physicians, consecutive inclusion in the study and the absence of selection bias due to physicians.

Even if questionnaires were developed through focus groups of doctors and patients to determine the items to be proposed, the study population could only choose between a restricted number of predetermined answers to express their opinion. Also, although patients and physicians were selected at random, as in previous comparable works, limitations of this survey relate typically to the reliability of physician and patient responses [17].

Finally, another limitation could be that patients had to have a diagnosis of hypercholesterolaemia 1 to 6 months before the start of the study.

Suggestions for improving patient education and risk perception are as follows:

- as seen before, cardiovascular risk is perceived inappropriately and underestimated by patients. Hence, doctors should pay particular attention to the way they communicate the notion of cardiovascular risk to their patients. Indeed, calculating cardiovascular risk and talking about it with the patient has been shown to improve the patient's health status [18];
- identifying patients' beliefs could also be a good opportunity to fight against preconceived ideas and promote the benefits of a balanced food diet. In particular, contrary to popular belief, there is no apparent reduction, but rather an improvement to a certain extent, in the quality of life and patient satisfaction with medical nutrition therapy for hypercholesterolaemia [19];
- in the long term, shared decision-making is a key element for efficacy.

Among doctors answering the present study, only 3.6% referred patients who needed dietetic care to a specialized practitioner. This is even less than in previous works, in which 14% of patients have been shown to be referred to dietitians [20]. However, among the potential difficulties encountered by doctors, the items 'the dietary advice I give them is not specific enough for hypercholesterolaemia' and 'there are no simple and steady rules regarding dietary advice' scored means of 4.6 and 4.1, respectively. These and other items indicate that doctors either do not feel specialized/knowledgeable enough to adequately advise their patients or do not have enough time and/or tools to provide efficient advice. Finally, patients clearly need practical information (how to cook, how to implement recommendations on a day to day basis) and this practical need is not well identified by physicians.

Conclusions

This survey, which addressed the question of patient adherence to dietary prescription in an original way, enabled physicians' and patients' opinions and perceptions regarding cholesterol-lowering diets to be compared, as well as

further exploring the quality of the doctor–patient relationship.

Disclosure of interest

S.A. Financial interests in the company Danone. S.A. Owner, manager, employee, part of decision-making body in the company Danone. C.M. Owner, manager, employee, part of decision-making body in the company EFICOM. E.B. Clinical trials: acting as main investigator, coordinator or main experimenter for Danone. D.P., S.A., C.M. Clinical trials: as co-investigator, secondary experimenter, collaborator in the study for Danone. E.B. One-off interventions: expert/survey report and advisory activity for Solvay, MSDSP, GENFIT, Novartis, Unilever, GSK, Pfizer, Astra Zeneca, Novonordisk, Danone, Lu-Kraft, Unilever, AMT, Genzyme and Lilly. D.P. One-off interventions: expert/survey report and advisory activity for MSD France SAS, Roche, ALK-Abelló, Reckitt Benckiser, Danone. E.B. Conferences: invitations as contributor for Danone, Astra Zeneca, Unilever, MSD. D.P. Conferences: invitations as contributor for Danone.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.acvd.2012.06.005>.

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